

Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
Walsh Pizzi O'Reilly Falanga LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Loly G. Tor
K&L Gates LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

*Attorney for Defendants Cipla USA, Inc. and
Cipla Ltd.*

*Attorneys for Plaintiffs
Teva Branded Pharmaceutical
R&D Inc. and Norton (Waterford) Ltd.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., and
NORTON (WATERFORD) LTD.,

Plaintiffs,

v.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

Civil Action No. 24-909 (SRC)(MAH)
(consolidated)

Civil Action No. 24-5856 (SRC)(MAH)

Civil Action No. 24-7162 (SRC)(MAH)

[PROPOSED] JOINT DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b)(2) and the Court's July 24, 2024 Order (Dkt. No. 17), Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., and Norton (Waterford) Ltd. (collectively, "Teva") and Defendants Cipla USA, Inc. and Cipla Ltd. (collectively, "Cipla") submit the following Joint Discovery Plan for the Court's consideration. On July 29, 2024, Plaintiffs' and Defendants'

counsel held a teleconference as required by Federal Rule of Civil Procedure 26(f) and Local Rule 26.1(b)(2).

- 1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.**

Attorneys for Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Liza M. Walsh
Selina M. Ellis
Hector D. Ruiz
Christine P. Clark
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
Phone: (973) 757-1100
Fax: (973) 757-1090

David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, S.W.
Washington, DC 20024
Phone: (202) 434-5000
Fax: (202) 434-5029

Attorneys for Cipla USA, Inc. and Cipla Ltd.

Loly G. Tor
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
Phone: (973) 848-4026
Fax: (973) 848-4001

Anil Patel
K&L GATES LLP
609 Main Street, Suite 4150
Houston, Texas 77002

Phone: (713) 815-7304

Elizabeth Weiskopf
Harold Storey
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, Washington 98104
Phone: (206) 623-7580

2. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.

This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., filed by Teva, which relate to Cipla's submission of Abbreviated New Drug Application ("ANDA") No. 219000, respectively, to the U.S. Food and Drug Administration ("FDA"). Cipla seeks approval to market generic versions of Teva's QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) drug product prior to the expiration of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), 11,583,643 (the "'643 patent"), 11,793,953 (the "'953 patent"), 11,865,247 (the "'247 patent"), 11,896,759 (the "'759 patent"), and 11,957,832 (the "'832 patent") (collectively, the "Patents-in-Suit"). Teva filed Civil Action No. 24-909 (*Cipla I*) on February 16, 2024 after receiving a Paragraph IV Notice Letter from Cipla with respect to twelve of the Patents-in-Suit: the '712 patent, the '476 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, the '447 patent, the '888 patent, the '889 patent, the '637 patent, and the '643 patent. Thereafter, Cipla sent Teva additional Paragraph IV Notice Letters regarding the '953 patent, the '247 patent, and the '759 patent, prompting Teva to file Civil Action No. 24-5856 (*Cipla II*). Thereafter, Cipla sent Teva a

further Paragraph IV Notice Letter regarding the '832 patent, prompting Teva to file Civil Action No. 24-7162 (*Cipla III*).

Teva asserts claims for infringement against Cipla for each of the Patents-in-Suit and seeks declaratory judgments of infringement and validity. Cipla denies Teva's claims of infringement and asserts counterclaims seeking a declaratory judgment of non-infringement and invalidity for each of the Patents-in-Suit.

3. Have settlement discussions taken place? Yes _____ No X.

4. The parties [have X have not _____] met pursuant to Fed. R. Civ. P. 26(f):

On July 29, 2024, Teva's and Cipla's counsel held a teleconference as required by Federal Rule of Civil Procedure 26(f) and Local Rule 26.1(b)(2). Local counsel for all parties were present on that call.

5. The parties [have _____ have not X] exchanged the information required by Federal Rule of Civil Procedure 26(a)(1). If not, state the reason therefor.

The parties will exchange information pursuant to Federal Rule of Civil Procedure 26(a)(1) as set forth in Appendix A.

6. Explain any problems in connection with completing the disclosures required by Fed. R. Civ. P. 26(a)(1).

The parties do not anticipate concerns regarding the exchange of information pursuant to Federal Rule of Civil Procedure 26(a)(1).

7. The parties [have _____ have not X] filed disclosures of third-party litigation funding. See Local Civil Rule 7.1.1.

8. The parties [have X have not _____] conducted discovery other than the above disclosures. If so, describe:

Cipla represents that it has produced portions of ANDA No. 219000 pursuant to Local Patent Rule 3.6(a).

9. Proposed joint discovery plan:

(a) Discovery is needed on the following subjects:

The parties contemplate taking discovery relating to the claims, counterclaims, and affirmative defenses in the parties' pleadings, including non-infringement/infringement and invalidity/validity of the patents-in-suit, as well as various related issues.

(b) Discovery [should ____ should not X] be conducted in phases.

The parties propose that expert discovery take place following the close of fact discovery. Otherwise, discovery should not be conducted in phases or be limited to particular issues.

(c) Proposed schedule

(1) Fed. R. Civ. P. 26 Disclosures ____.

See Appendix A

(2) E-Discovery conference pursuant to L. Civ. R. 26.1(d) ____.

See Appendix A.

(3) Service of initial written discovery ____.

The parties will commence service of written discovery as provided by Exhibit A.

(4) Maximum number of interrogatories by each party to each other party.

The parties agree that no side shall serve more than 25 interrogatories collectively. Thus, Teva shall serve no more than 25 interrogatories on Cipla, and Cipla shall serve no more than 25 interrogatories on Teva. The parties agree to confer in good faith should more than 25 interrogatories be required by either party.

(5) Maximum number of depositions to be taken by each party:

The parties agree that Teva shall take no more than 10 fact depositions. Cipla shall take no more than 10 fact depositions. If a party needs to exceed the 10 fact deposition limit, the parties shall confer in good faith to resolve the issue.

A deposition notice under Federal Rule of Civil Procedure 30(b)(6) shall count as 1 deposition. Unless the parties agree otherwise, depositions shall be limited to 7 hours. The parties agree that the amount of time required for a Rule 30(b)(6) deposition (from a single notice) should not be limited to 7 hours. The parties will work in good faith to agree on the number of hours for which a single witness who has been designated as a 30(b)(6) witness and noticed in his personal capacity may be deposed, and to endeavor to limit the depositions of each such witness to 7 hours. The limitation on the number of depositions does not apply to expert depositions.

Location of depositions: The parties will confer on the most efficient way to proceed with depositions of domestic and foreign witnesses or requests to obtain foreign documents. The parties will work together to schedule depositions at mutually agreeable times and locations and will confer on the most efficient way to proceed with depositions (remote or in-person).

(6) Motions to amend or add parties to be filed by ____.

See Appendix A.

(7) Factual discovery to be completed by ____.

See Appendix A.

(8) Plaintiff's expert report due on ____.

See Appendix A.

(9) Defendant's expert report due on ____.

See Appendix A.

- (10) Expert discovery to be completed by ____.**

See Appendix A.

- (11) Dispositive motions to be served within ____ days of completion of discovery.**

Because this case will not be tried before a jury, and given the nature of the parties' disputes, dispositive motions shall not be permitted except by leave of Court. Any request for permission to file a dispositive motion must be submitted within 7 days of completion of discovery.

- (d) Set forth any special discovery mechanism or procedure requested.**

As set forth in Appendix A, the parties shall jointly propose a Discovery Confidentiality Order.

- (e) A pretrial conference may take place on ____.**

See Appendix A.

- (f) Trial Date _____. (_____ Jury Trial ; X Non-Jury Trial).**

See Appendix A.

- 10. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of state witnesses or documents, etc.)? Yes X No _____. If so, explain.**

The parties are currently investigating the need for discovery from individuals and entities located outside the United States, including current and former employees, and entities that manufacture and/or test the relevant portions of either party's product, and/or submitted letters as part of Defendants' ANDA or Teva's NDA.

- 11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?**
Yes _____ No X . If so, explain.

The parties anticipate producing electronically stored information but currently do not expect disputes to arise with respect to the form or forms in which such information should be produced.

If so, how will electronic discovery or data be disclosed or produced? Describe any agreements reached by the parties regarding same, including costs of discovery, production, related software, licensing agreements, etc.

The parties will endeavor to reach agreement regarding the custodial sources to be searched by each party, the search terms applied to those sources, and the format of any resulting production.

- 12. Do you anticipate entry of a Discovery Confidentiality Order? See L. Civ. R. 5.3(b) and Appendix S.**

As set forth in Appendix A, the parties shall jointly propose a Discovery Confidentiality Order (“DCO”). Until the Court enters a DCO in this matter, the parties will follow the confidentiality procedures of L. Pat. R. 2.2. If the parties cannot agree, then they will request the Court’s assistance.

- 13. Do you anticipate any discovery problem(s) not listed above? Describe.**
Yes _____ No X .

- 14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).**

The parties do not believe that this case is appropriate for voluntary arbitration, mediation, appointment of a special master, or other special procedure. The parties fundamentally disagree about the merits of each other's claims and counterclaims.

- 15. Is this case appropriate for bifurcation? Yes _____ No X.**

- 16. An interim status/settlement conference (with clients in attendance) should be held in _____.**

The parties do not believe an interim settlement conference is necessary. The parties are sophisticated parties who can evaluate whether discussions will be productive, and will seek the Court's assistance if and when it seems appropriate. The parties understand the Court will hold status conferences at regular intervals.

- 17. We do _____ do not X consent to the trial being conducted by a Magistrate Judge.**

The parties do not consent to the trial being conducted by a Magistrate Judge.

- 18. Identify any other issues to address at the Rule 16 Scheduling Conference.**

The parties do not anticipate any other issues that will need to be addressed at the Rule 16 Scheduling Conference.

- 19. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the Rule 26(f) conference:**

- (a) Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3);**

See Appendix A.

- (b) The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the Court;**

See Appendix A.

- (c) The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing.**

The parties will submit this information in a Joint Claim Construction and Prehearing Statement. *See* Appendix A.

- (d) How the parties intend to educate the Court on the patent(s) at issue.**

The parties intend to educate the Court on the Patents-in-Suit through at least submissions to the Court and/or by technology tutorial(s) presented at the Court's request in advance of claim construction argument.

- (e) The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2);**

As set forth in Appendix A, the parties shall jointly propose a Discovery Confidentiality Order.

- (f) The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results);**

Teva's investigation regarding the availability and timing of production of invention records is ongoing.

- (g) The availability and timing of production of ANDA product research and development documents**

The proposed timing of compliance with L. Pat. R. 3.2A is governed by the schedule set forth in Appendix A. To the extent any ANDA product research and development documents falling outside the scope of L. Pat. R. 3.2A exist, are within Cipla's possession, custody, or control, are relevant to any party's claims or defenses, are non-duplicative and proportional to the needs of the case; and are timely requested,

Defendants will produce any non-privileged research and development documents pursuant to a reasonable search and prior to the deadline for the substantial completion of document production set forth in Appendix A.

(h) The availability and timing of production of ANDA product samples;

The parties will confer regarding, among other things, the availability and timing of the production of ANDA product samples that may be requested by Plaintiffs.

(i) The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;

Teva will provide the information required by the Local Patent Rules with its contentions.

(j) Each inventor's availability for deposition in the matter;

Teva's investigation regarding the inventors' availability for deposition is ongoing. The parties will meet and confer to discuss depositions at the appropriate stage in the litigation.

(k) Availability of foreign witnesses for deposition and foreign documents;

Teva and Cipla contemplate that they may need to depose foreign witnesses and/or produce foreign documents. The parties are investigating the availability of foreign witnesses and documents relevant to this proceeding.

(l) Whether there is a 30-month stay and if so, when it ends;

The 30-month stay date for Civil Action No. 24-909 ends no earlier than July 5, 2026. There is no 30-month stay associated with Civil Action Nos. 24-5856 or 24-7162.

(m) A date for substantial completion of document production and a method for determining compliance;

See Appendix A.

(n) Any other issues or matters that a party believes are time sensitive.

None.

Appendix A

<u>Event</u>	<u>Compromise Proposal</u>
Scheduling Conference	8/5/2024
Rule 26(a)(1) Disclosures	8/9/2024
Joint Proposed Discovery Confidentiality Order	8/16/2024
Plaintiffs Identify Asserted Claims pursuant to L. Pat. R. 3.6(b)	8/29/2024
Defendants Serve Non-Infringement/Invalidity Contentions and Accompanying Document Production Under L. Pat. R. 3.4(b), 3.4(c), 3.6(f)	10/31/2024
Plaintiffs Serve Infringement Contentions/Responses to Invalidity Contentions and Accompanying Document Production Under L. Pat. R. 3.2, 3.4A(e)	12/20/2024
Parties Exchange Proposed Claim Terms for Construction	1/8/2025
Parties Exchange Preliminary Proposed Claim Constructions and Identify Intrinsic and Extrinsic Evidence	1/22/2025
Parties Meet and Confer to Narrow Claim Construction Issues and Finalize Joint Claim Construction and Prehearing Statement	2/10/2025
Joint Claim Construction and Prehearing Statement	2/14/2025
Completion of (Non-Expert) Claim Construction Discovery	2/28/2025

Opening Claim Construction Briefs (Including any Opening Expert Declarations)	3/14/2025
Completion of Expert Discovery Relating to Opening Expert Declarations Regarding Claim Construction	3/28/2025
Responsive Claim Construction Briefs (Including any Responsive Expert Declarations)	4/18/2025
Joint Proposed Schedule for Claim Construction Hearing	4/25/2025
Claim Construction Hearing	May 2025 (Subject to the Court's availability)
Summary Judgment Motions	None without Leave of Court
Document Production Substantially Complete	5/2/2025
Deadline to Amend Pleadings/Add Parties	5/16/2025
Close of Fact Discovery	7/23/2025
Opening Expert Reports on Issues for Which a Party Bears the Burden of Proof	8/29/2025
Responsive Expert Reports (Including Opening Expert Reports on Objective Indicia of Non-Obviousness)	10/17/2025
Reply Expert Reports (Including Responsive Expert Reports on Objective Indicia of Non-Obviousness)	11/14/2025
Close of Expert Discovery	12/5/2025
Opening <i>Daubert</i> Briefs	12/12/2025

<i>Daubert</i> Briefs in Opposition	12/19/2025
<i>Daubert</i> Reply Briefs	12/30/2025
Pre-Trial Brief	1/16/2026
Joint Pretrial Order	1/21/2026
Pretrial Conference	February 2026 (Subject to the Court's availability)
Trial	February 2026 (Subject to the Court's availability)
30-Month Stay Expires	July 5, 2026